ENVIRONMENT DIRECTORATE
Environment, Health and Safety Division

ENV/EHS/PA/as/2009.19 Paris, 16 December 2009

To: Working Group of National Co-ordinators of the Test Guidelines Programme (WNT)

***SUBJECT:* THE THREE DRAFT LLNA TEST GUIDELINES FOR COMMENTS**

Dear Madam/Sir,

Please find attached the three proposals for revised versions of the Local Lymph Node Assay (LLNA) Test Guideline 429 for your consideration. The drafts are: (i) the traditional LLNA with added Performance Standards (PS), (ii), a non-radioactive LLNA test method called the "DA-version", and (iii), a 2nd non-radioactive LLNA test method called the "BrdU-ELISA version"(projects led by Japan and USA).

The first versions were circulated to the WNT for comments on 10 July 2009 with a deadline of 28 August and comments have been received from UK, DMK, IRL, DEU, CAN, JPN, SE, AUT, EC, ICAPO and BIAC. Since many of the comments were rather significant the Secretariat arranged for an Expert Consultation Meeting, kindly hosted by the US Consumer Product Safety Commission (CPSC) and US NICEATM-ICCVAM and it was held on 20-22 October in Washington DC.

The meeting focused on resolving the issues from the commenting round and the issues for the updated LLNA receiving most attention included; (i) the LLNA PS; (ii) the suggested irritant pre-screen; (iii) the reduced LLNA, and (iv), whether pooled or individual lymph nodes should be used. For the LLNA DA/BrdU-ELISA test methods the absolutely most difficult issues were whether single or dual decision criterion should be used, in addition to whether the two Japanese methods could be applicable to "me-too" validation applying the LLNA PS. The decision criteria could not be concluded at the meeting since data for a proper review was not available at the time. Regarding the PS validation, the meeting did investigate this quite thoroughly but concluded that even though being rather similar there were simply too much dissimilarity and the two methods should be stand-alone methods on their own merits. They have been individually validated and at the meeting new information of additionally tested chemicals was presented. Time at the meeting did not allow going through all the comments from member countries in detail so participants agreed to continue working on the issues raised by the meeting and reconvene in a telephone conference call in early December to try to resolve all remaining issues.

The Secretariat arranged for a conference call on December 1 to address all remaining issues raised by the meeting in addition to all comments from member countries. US NICEATM-ICCVAM had prepared a list of actions based on the meeting discussions and the minutes from the conference call has been attached to the LLNA Expert Meeting Report, which can be downloaded from the protected website (*then go to the LLNA Expert Meeting!)*.

2, rue André-Pascal
75775 Paris Cedex 16, France
www.oecd.org/ehs
Patric.Amcoff@oecd.org
Direct line
Tel.: +33 (0) 1 45 24 16 19
Fax.: +33 (0) 1 44 30 61 80

The draft Test Guidelines are available on the public Website:

[http://www.oecd.org/document/55/0,3343,en_2649_34377_2349687_1_1_1_1,00.html]

Test Guidelines with tracked changes and compilation of comments with responses are available on the Protected Website, under "*Draft Test Guidelines*", please note that some of the comments for the LLNA DA/BrdU-ELISA are duplicated in all three compilations of comments.

I would thereby like to invite National Co-ordinators to review the draft Test Guidelines. Your comments are requested ***by the very latest 27 January 2010***, and if no comments are received the Secretariat considers this as silent approval to the present drafts.

Please don't hesitate to contact me if you have any questions or concerns.

Yours sincerely,

Patric Amcoff
Principal administrator
Environment, Health and Safety Division

Cc: European Commission (DGs Environment, Enterprise, Sanco, Science, JRC, ECVAM)
BIAC (including ACC, CEFIC, Croplife International, ECETOC, JCIA)
EEB, ICAPO, ILSI Europe/North America, IPCS, UNECE, ILO, IFCS, TUAC
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